UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

ROBERT ETTEN, on behalf of themselves and all other similarly situated, Plaintiff, vs. JOHNSON & JOHNSON CONSUMER, INC., AND THE PROCTOR & GAMBLE CO., Defendants.	Case No. 0:23-cv-03471 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMAND**

Plaintiff Robert Etten ("Plaintiff"), on behalf of himself and all others similarly situated, file this Class Action Complaint ("CAC") against Defendants Johnson & Johnson Consumer, Inc., and The Proctor & Gamble Company (collectively "Defendants") and in support states the following:

NATURE OF THE ACTION

1. This is a class action lawsuit brought under Minnesota's consumer protection laws by Plaintiff, and others similarly situated, who purchased the following over-the-counter ("OTC") oral decongestant products containing phenylephrine: Sudafed PE, Vicks NyQuil Severe, and Vicks DayQuil Severe (collectively the "Products"). These Products are manufactured, sold and distributed by Defendants and have been found by the U.S. Food and Drug Administration ("FDA") to lack efficacy.[1] The Products' lack of efficacy

[1] *Final Summary Minutes of the Nonprescription Drugs Advisory Committee Meeting*

was not disclosed to Plaintiff prior to Plaintiff's purchase of the Products. Plaintiff would not have purchased the Products had he known they did not work as advertised.

2. Plaintiff and the putative class suffered economic damages due to Defendants' misconduct (as set forth below) and they seek injunctive relief and restitution for the full purchase price of the Products they purchased. Plaintiff alleges the following based upon personal knowledge as well as investigation by counsel, and as to all other matters, upon information and belief. Plaintiff further believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

JURISDICTION AND VENUE

3. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which there are an excess of 100 class members and Plaintiff is a citizen of a state different from Defendants.

4. This Court has jurisdiction over each Defendant because both Defendants are authorized to conduct and do conduct business in Minnesota. Defendants have marketed, promoted, distributed, and sold the Products in Minnesota and Defendants have sufficient

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September 11–12, 2023, FDA, 6, https://www.fda.gov/media/172701/download (hereinafter *Final Summary*) (recording vote on the question "Do the current scientific data that were presented support that the monograph dosage of orally administered phenylephrine is effective as a nasal decongestant?" with 0 "yes" votes, 16 "no" votes, and no abstentions); *see also* Nonprescription Drugs Advisory Committee, *Briefing Document: Efficacy of Oral Phenylephrine as a Nasal Decongestant*, FDA (Sept. 2023), https://www.fda.gov/media/171915/download (hereinafter *NDAC Briefing Document*).

minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

5. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred while he resided in this judicial district. Venue is also proper under 18 U.S.C. §1965(a) because Defendants transact substantial business in this District.

THE PARTIES

6. Plaintiff Robert Etten is a citizen and resident of Minnesota. Within the class period defined below, Plaintiff purchased Johnson & Johnson Sudafed PE, Vicks NyQuil Severe, and Vicks DayQuil Severe from Super Target and Walgreens stores located in Ramsey County, Minnesota. During that time, based on the false and misleading claims by Defendants, Plaintiff was unaware that Defendants' Products were not an effective remedy for congestion and/or cold symptoms. Plaintiff purchased the Defendants' Products on the assumption that the labeling of the Products was accurate and that the Products worked as advertised. Plaintiff would not have purchased Defendants' Products had he known they were not effective and lacked efficacy. As a result, Plaintiff suffered injury in fact when he spent money to purchase Products he would not otherwise have purchased absent Defendants' misconduct, as alleged herein.

7. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with headquarters and principal place of business in the State of New Jersey. At all times relevant to this complaint, Johnson & Johnson was engaged in the business of

manufacturing, marketing, testing, promoting, selling, and/or distributing oral phenylephrine products.

8. Defendant The Proctor & Gamble Company ("Proctor & Gamble" or "P&G") is an Ohio corporation with headquarters and principal place of business at One Procter & Gamble Plaza, Cincinnati, Ohio 45202. At all times relevant to this complaint, Proctor & Gamble was engaged in the business of manufacturing marketing, testing, promoting, selling, and/or distributing oral phenylephrine products.

9. Defendant Proctor & Gamble owns and controls the Vicks brand of OTC products.

INTRODUCTION

10. Defendant J&J is a corporation engaged in the manufacture, marketing, and sale of various oral OTC pharmaceutical products that include phenylephrine, including Sudefed PE.

11. Defendant P&G is a corporation engaged in the manufacture, marketing, and sale of various oral OTC pharmaceutical products that include phenylephrine through the Vicks brand of products. These Products include Vicks NyQuil Severe and Vicks DayQuil Severe.

12. Defendants marketed and sold the Products to consumers in Minnesota and across the United States as an effective nasal decongestant.

13. The main active ingredient in the Products is phenylephrine hydrochloride, or "PE."

14. In 1994, the FDA issued a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective ("GRASE") and not misbranded. Phenylephrine is included in the final monograph as an OTC oral nasal decongestant.

15. Defendants marketed PE as an effective decongestant that should be used to relieve nasal congestion and sinus pressure associated with colds, allergies, and other respiratory conditions.

16. According to Defendants, phenylephrine works by constricting blood vessels in the nasal passages, which reduces swelling and congestion.

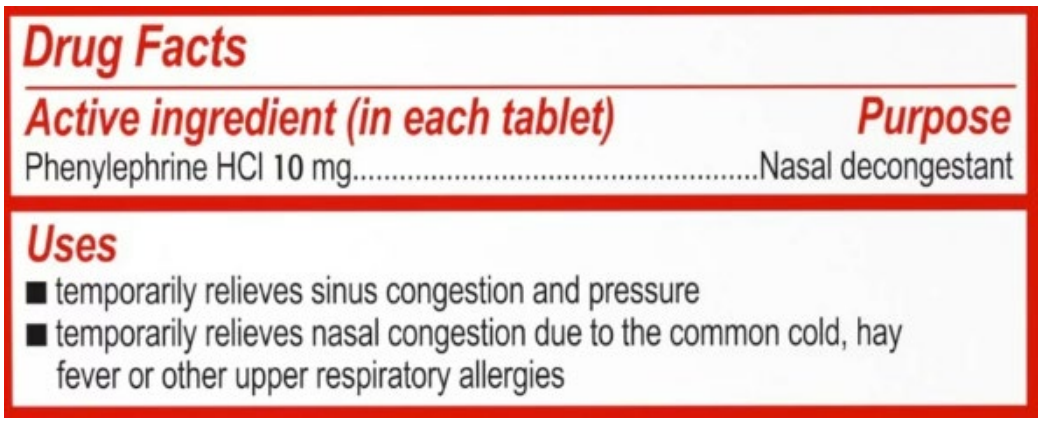
17. Over the years, Defendants made the following claims on their marketing materials concerning the efficacy of their Products:

18. For Johnson & Johnson's Sudafed PE, the packaging lists the "Purpose" of the drug as a "nasal decongestant" (see below). The packaging also includes the below claims:

(a) "Maximum Strength" relief from "Sinus Pressure" and "Sinus Congestion"[2]

(b) "[T]emporarily relieves sinus congestion and pressure"[3]

[2] Source: https://www.walmart.com/ip/Sudafed-PE-Maximum-Strength-Non-Drowsy-Sinus-Decongestant-18Ct/45809357.
[3] *Id.*



19. Similarly, for Vick's NyQuil Severe, the packaging lists the "Purpose" of the drug as a "nasal decongestant" (see below). The packaging also includes the below claims:

(a) "Max Strength" relief from "Nasal Congestion & Sinus Pressure"[4]

(b) "temporarily relieves common cold/flu symptoms" including "nasal congestion" and "sinus congestion & pressure"[5]

[4] Source: https://www.cvs.com/shop/vicks-nyquil-severe-cough-cold-flu-relief-24-liquicaps-prodid-451200?skuId=451200&cgaa=QWxsb3dHb29nbGVUb0FjY2Vzc0NWU1BhZ2Vz&cid=ps_ur_pla_test&gclid=EAIaIQobChMIzN7ZhPPhgQMVYw2tBh1MEQrLEAQYASABEgIa6PD_BwE&gclsrc=aw.ds

[5] *Id.*

Drug Facts

Active ingredients (in each LiquiCap)	Purpose
Acetaminophen 325 mg	Pain reliever/Fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

20. Phenylephrine is one of two compounds found in nasal decongestant products that can be readily found for sale in stores without a prescription. The other compound is pseudoephedrine, or "PSE," which the FDA also identified as a GRASE oral

nasal decongestant in the 1994 Final Monograph. However, unlike PE, PSE has been found to be an effective oral nasal decongestant.[6]

21. Unfortunately, pseudoephedrine is often used as an ingredient in making illicit methamphetamine and, after the passage of the Combat Methamphetamine Epidemic Act of 2005 ("CMEA"), PSE became regulated as a "behind-the-counter" compound.

22. This change in classification led some manufactures to reformulate OTC products previously containing PSE to instead only include PE.

23. Products containing PSE are comparatively more inconvenient for customers to obtain. The relative ease of obtaining oral nasal decongestants that contain only PE make those products naturally more desirable.

24. In 2007, the consumer advocacy group Public Citizen filed a petition with the U.S. Food and Drug Administrations (FDA) regarding PE. The petition requested that the FDA re-evaluate the safety and efficacy of phenylephrine as a nasal decongestant and take regulatory action.

25. Public Citizen expressed concerns that PE, the active ingredient in many OTC decongestant products, was not as effective as PSE.

26. The petition argued that the switch from PSE to PE in many cold and allergy medications had not been supported by adequate scientific evidence demonstrating the latter's effectiveness in relieving nasal congestion.

[6] *See, e.g.*, Chua, SS and SI Benrimoj, 1988, Non-prescription sympathomimetic agents and hypertension, Med Toxicol Adverse Drug Exp, 3(5):387-417.

27. Public Citizen also raised concerns about the potential side effects and safety of PE, suggesting that its use might lead to increased blood pressure in some individuals.

28. The FDA reviewed the concerns raised by the Public Citizen petition regarding the safety and efficacy of PE as a nasal decongestant. The FDA concluded that, based on the available data at the time of its review in 2007, phenylephrine could be considered effective as a nasal decongestant when used at the recommended doses.

29. Thus, in 2007, the FDA concluded that orally administered PE was Generally Recognized as Safe and Effective (GRASE).

30. The FDA's GRASE determination allowed Defendants to market the Products as an OTC or "over-the-counter" medication. This was an important designation to Defendants as it allowed them to market the Products to consumers without requiring a doctor's prescription, making it more accessible for self-treatment, and allowing Defendants to make billions of dollars in OTC sales.

31. However, the NDAC convened on September 11th and 12th, 2023 to discuss efficacy of PE, and released an accompanying briefing document detailing the NDAC's updated review of the efficacy of PE, based on the studies it initially reviewed in 2007 and additional studies obtained since its initial review.[7]

32. At its initial 2007 Nonprescription Drugs Advisory Committee ("NDAC") meeting and review, the FDA reviewed clinical effectiveness data for oral doses between

[7] *See Final Summary*, 2.

5mg and 40mg in a total of 14 studies, of which 7 reported positive measurable efficacy results.

33. In its re-analysis of these studies in 2023, the FDA found significant problems:

> [w]hen considering the studies through a modern drug review lens, all of the studies (both positive and negative) were highly problematic in both design and methodology. All used a highly variable endpoint (NAR) to study a drug in the setting of a highly variable disease state (the common cold) that is no longer used as a primary endpoint to evaluate congestion in pivotal trials.[8] Further, ***all the positive studies*** (and most of the negative studies) ***were unpublished and therefore never peer-reviewed***. Six of the seven positive studies came from ***a single study center*** (funded by the manufacturer of Neo-Synephrine), were ***very small in size***, and (except in one instance) the results ***could not be duplicated*** at two other study centers (also funded by the same manufacturer) that used a similar study design and methodology.[9]

34. The FDA thus found that the original studies had data integrity issues and that the results from the Elizabeth study site, a study it relied on in 2007, could not be duplicated in at least two other Sterling-Winthrop study sites that used a similar study design and methodology.

[8] The FDA's Guidance for Industry on Developing Drug Products for Treatment of Allergic Rhinitis recommends use of symptom scores for the primary endpoint in clinical trials. *See* FDA, 2018, Guidance for Industry; Allergic Rhinitis: Developing Drug Products for Treatment, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/allergic-rhinitis-developing-drugproducts-treatment-guidance-industry (hereafter "FDA Guidance for Industry (2018)").

[9] *NDAC Briefing Document*, 54–55 (emphasis added).

35. As noted in the FDA's re-evaluation of the data, the original studies used to support the GRASE determination in 2007 were based on "equivocal findings."[10]. Indeed, there were "significant deficiencies" in the "design and conduct of these studies."[11]

36. In light of the methodological and design flaws it found, the FDA now believes that "the original studies evaluated for efficacy" are "unacceptable as continued support for the efficacy of monographed doses or oral PE."[12]

37. Since 2007, several additional large clinical trials have been conducted regarding the efficacy of phenylephrine.[13] Those studies provide evidence of the absence of a decongestant effect from the OTC approved doses of 10 mg.

38. For example, Horak et al (2009) found that PE was not significantly different from placebo in the mean change in subjective nasal congestion scores whereas PSE, a

[10] *Id.* at 56.
[11] *Id.*
[12] *Id.* at 55.
[13] *See, e.g.*, Gelotte, CK and BA Zimmerman, 2015, Pharmacokinetics, safety, and cardiovascular tolerability of phenylephrine HCl 10, 20, and 30 mg after a single oral administration in healthy volunteers, Clin Drug Investig, 35(9):547-558; Day, JH, MP Briscoe, JD Ratz, M Danzig, and R Yao, 2009, Efficacy of loratadine-montelukast on nasal congestion in patients with seasonal allergic rhinitis in an environmental exposure unit, Ann Allergy Asthma Immunol, 102(4):328-338; Horak, F, P Zieglmayer, R Zieglmayer, P Lemell, R Yao, H Staudinger, and M Danzig, 2009, A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Chamber, Ann Allergy Asthma Immunol, 102(2):116-120; Meltzer, EO, PH Ratner, and T McGraw, 2015, Oral phenylephrine HCl for nasal congestion in seasonal allergic rhinitis: A randomized, open-label, placebo-controlled study, J Allergy Clin Immunol Pract, 3(5):702-708; Meltzer, EO, PH Ratner, and T McGraw, 2016, Phenylephrine hydrochloride modified-release tablets for nasal congestion: a randomized, placebo-controlled trial in allergic rhinitis patients, Ann Allergy Asthma Immunol, 116(1):66-71.

positive control in the study, decreased congestion significantly greater than placebo and PE.

39. Day et al (2009) similarly reported no difference between PE and placebo with respect to decreased nasal congestion scores.

40. Gelotte and Zimmerman (2015) likewise reported a lack of local decongestion effect of PE, finding that doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant.

41. Thus, the results of several studies reported after the initial efficacy determination of the Products in 2007 clearly demonstrate that PE is no more effective than placebo in decreasing nasal congestion and, thus, lacks efficacy.

42. On September 12, 2023, an FDA panel unanimously declared that PE, the active ingredient in the Products, is an ineffective decongestant.

43. As of 2007, nasal airway resistance ("NAR") was the principal methodology used to assess the effectiveness of oral PE. This methodology used measurements of airflow and air pressure in the nasal passage to calculate NAR as an indirect measure of the level of nasal congestion.

44. In 2018, however, the FDA issued new guidance for industry as it related to the use of nasal congestion symptom scores to evaluate congestion,[14] meaning that NAR was no longer used as a primary endpoint to evaluate congestion in studies.

[14] FDA Guidance for Industry (2018).

45. Based on the FDA's new 2018 guidance, Defendants knew or should have known that their marketing claims regarding the Products' efficacy were false and misleading. This is because the primary endpoint for evaluating the efficacy of the Products had changed since the FDA's 2007 NDAC meeting, meaning that the previous data under which the Products were approved as GRASE no longer supported efficacy. There have been no published studies since the FDA's revised 2008 guidance for industry was released that demonstrate the effectiveness of oral phenylephrine as a decongestant. Accordingly, Defendants knew or should have known by at least 2018 that their marketing claims regarding the Products' efficacy were false and misleading.

46. Plaintiff and the class members purchased the Products in reliance on Defendants' false and deceptive marketing claims.

47. As a result of Defendants' false and deceptive marketing, Plaintiff and the class members suffered economic damages, including the cost of purchasing the Products.

CLASS ALLEGATIONS

48. Plaintiff brings this action on behalf of himself and all other similarly situated class members (the "Class" or "Classes") pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class against Defendants for violations of Minnesota state laws and/or similar laws in other states:

Multi-State Class Action

> All consumers who purchased Defendants' oral phenylephrine products in the United States of America and its territories (excluding California) from September 13, 2018 to the present for personal use or consumption.

> Excluded from the Class are individuals who allege personal bodily injury resulting from the use of collective Defendants oral phenylephrine products. Also excluded from this Class are Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

49. In the alternative, Plaintiff brings this action on behalf of himself and all other similarly situated Minnesota consumers pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Sub-Classes:

> **Minnesota Sub-Class**
>
> All consumers who purchased Defendants' oral phenylephrine products in the State of Minnesota from September 13, 2018 to the present for personal use or consumption.
>
> Excluded from the Class are individuals who allege personal bodily injury resulting from the use of Defendants' oral phenylephrine products. Also excluded from this Class are Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

50. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed and believes that the proposed Class/Sub-Classes contains thousands of purchasers of Defendants' Products who have been damaged by Defendants' conduct as alleged herein. The precise number of Class members is unknown to Plaintiff at this time.

51. Plaintiff's claims are typical to those of all Class members because members of the Class are similarly injured through Defendants' uniform misconduct described above and were subject to Defendants' deceptive marketing claims that accompanied each and

every Product. Plaintiff is advancing the same claims and legal theories on behalf of themselves and all members of the Class/Sub-Class.

52. Plaintiff's claims raise questions of law and fact common to all members of the Class, and they predominate over any questions affecting only individual Class members. The claims of Plaintiff and all prospective Class members involve the same alleged defect. These common legal and factual questions include the following:

(a) whether Defendants' Products contained PE;

(b) whether Defendants' marketing statements are false, misleading, or objectively reasonably likely to deceive;

(c) whether the alleged conduct constitutes violations of the laws asserted;

(d) whether Defendants' alleged conduct violates public policy;

(e) whether Defendants engaged in false or misleading advertising;

(f) whether Defendants were unjustly enriched as a result of its labeling, marketing, advertising and/or selling of the Products;

(g) whether Plaintiff and the Class members are entitled to damages and/or restitution and the proper measure of that loss; and

(h) whether an injunction is necessary to prevent Defendants from continuing to market and sell Products that lack efficacy.

53. Plaintiff and his counsel will fairly and adequately protect and represent the interests of each member of the class. Plaintiff has retained counsel experienced in complex litigation and class actions. Plaintiff's counsel has successfully litigated other class action cases similar to that here and have the resources and abilities to fully litigate and protect

the interests of the class. Plaintiff intends to prosecute this claim vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class, nor is Plaintiff subject to any unique defenses.

54. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by the Plaintiff and individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. It would thus be virtually impossible for Plaintiff and Class members, on an individual basis, to obtain meaningful and effective redress for the wrongs done to them. Further, it is desirable to concentrate the litigation of the Class members' claims in one forum, as it will conserve party and judicial resources and facilitate the consistency of adjudications. Plaintiff knows of no difficulty that would be encountered in the management of this case that would preclude its maintenance as a class action.

55. The Class also may be certified because Defendants have acted or refused to act on grounds applicable to the Class, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

56. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Defendant from engaging in the acts described above, such as continuing to market and sell Products that lack efficacy, and requiring Defendants to provide a full refund of the purchase price of the Products to Plaintiff and Class members.

57. Unless a Class is certified, Defendants will retain monies received as a result of their conduct that were taken from Plaintiff and the Class members. Unless a Class-wide injunction is issued, Defendants will continue to commit the violations alleged and the members of the Class and the general public will continue to be misled. Indeed, to this day, Defendants continues to market and sell the Products that have been determined by a unanimous FDA panel to lack efficacy.

FIRST CAUSE OF ACTION

Violation of Minnesota's Deceptive Trade Practices Act

Minn. Stat. §§ 325D.43–325D.48

(On Behalf of the Plaintiff and the Minnesota Sub-Class Against All Defendants)

58. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

59. Plaintiff brings this Count individually and on behalf of the Minnesota Sub-Class.

60. The Minnesota Deceptive Trade Practices Act ("MDTPA") renders unlawful acts constituting representation that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have as well as engaging in any other conduct which similarly creates a likelihood or confusion or of misunderstanding. Minn. Stat. § 325D.44, subd. 1.

61. As alleged herein, Plaintiff and the Sub-Class members have suffered injury in fact as a result of Defendants' conduct because they purchased Products from Defendants in reliance on Defendants' representation that the Products were effective.

62. As alleged herein, Defendants' actions are deceptive and in clear violation of MDTPA, entitling Plaintiff and the Sub-Class to damages and relief under Stat. § 325D.44, subd. 1.

63. Defendants have engaged, and continue to engage, in conduct that is likely to deceive members of the public. This conduct includes representing in their labels that their Products are effective, which is untrue.

64. Similarly, Defendants have engaged, and continue to engage, in deceptive, untrue, and misleading advertising as described above.

65. By committing the acts alleged above, Defendants have engaged in unconscionable, deceptive, or unfair acts or practices, which constitute unfair competition within the meaning of MDTPA.

66. Defendants' conduct is substantially injurious to consumers. Consumers are purchasing using Defendants' Products without knowledge that they lack efficacy. This conduct has caused, and continues to cause, substantial injury to consumers because consumers would not have paid for nasal decongestant Products that do not work as advertised but for Defendants' false labeling, advertising, and promotion.

67. Indeed, no benefit to consumers or competition results from Defendants' conduct. Since consumers reasonably rely on Defendants' representation that the Products work as advertised, consumers could not have reasonably avoided such injury.

68. Minnesota Statute 325D.45, subd. 1, creates a private right of action for individuals likely to be damaged by a deceptive trade practice of another.

69. Minnesota Statute 325D.45, subd. 2, provides that the prevailing party in litigation arising from a cause of action pursuant to Chapter 325D shall be entitled to recover attorney's fees within the limitations set forth therein form the non-prevailing party.

70. Minnesota Statute 325D.45, subd. 3, provides that any remedies available under Chapter 325D are in addition to any other remedies otherwise available for the same conduct under state or local law.

71. As a result of Defendants' unfair and deceptive trade practices, Plaintiff and the Sub-Class members are entitled to an award of attorney's fees pursuant to MDTPA, Minnesota Statute 325D.45, subd. 2, if he prevails.

72. Wherefore, Plaintiff, and the Minnesota Sub-Class, pray for judgement against Defendants, as set forth hereafter. Defendants' conduct with respect to the labeling, advertising, marketing, and sale of their Products is unfair because Defendant' conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

73. In accordance with MDTPA,[15] Plaintiff and the Minnesota Sub-Class, seek an order enjoining Defendants from continuing to conduct business through fraudulent or unlawful acts and practices and to commence a corrective advertising campaign.

[15] Section 325D.45, subd. 1, allows "person likely to be damaged by a deceptive trade practice of another may be granted an injunction against it under the principles of equity and on terms that the court considers reasonable." Minn. Stat. 325D.45, subd. 1.

Defendants' conduct is ongoing and continuing, such that prospective injunctive relief is necessary.

74. On behalf of Plaintiff and the Minnesota Sub-Class, Plaintiff also seeks an order entitling them to recover all monies spent on the Defendants' Products, which were acquired through acts of fraudulent, unfair, or unlawful competition.[16] In addition, the measure of restitution should be full refund of the purchase price insofar as the Products and their associated labels are worthless. But for Defendants' misrepresentations and omissions, Plaintiff and Sub-Class members would have paid nothing for Products that do not work as advertised. Indeed, there is no discernible "market" for an over-the-counter nasal decongestant that is no more effective than a placebo at decreasing congestion. As a result, the Defendant's Products are rendered valueless.

75. Wherefore, Plaintiff and members of the Minnesota Sub-Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the Products.

SECOND CAUSE OF ACTION

Violation of Minnesota's Consumer Fraud Act

Minn. Stat. §§ 325F.69–325F.70

(On Behalf of the Plaintiff and the Minnesota Sub-Class Against All Defendants)

76. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

[16] Section 325D.45, subd. 2, provides that "costs shall be allowed to the prevailing party" and "the court may award attorneys' fees to the prevailing party…." Minn. Stat. 325D.45, subd. 2.

77. Plaintiff brings this Count individually and on behalf of the Minnesota Sub-Class.

78. The Minnesota Consumer Fraud Act ("MCFA") prohibits: "The act, use, or employment by any person of any fraud, unfair or unconscionable practice, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby…." Minn. Stat. 325F.69, subd. 1.

79. Defendants have engaged, and continue to engage, in conduct that is likely to deceive members of the public. This conduct includes representing in their labels that their Products are effective, which is untrue.

80. Similarly, Defendants have engaged, and continue to engage, in false and misleading advertising as described above.

81. By committing the acts alleged above, Defendants have engaged in unconscionable, deceptive, or unfair acts or practices, which constitute consumer fraud within the meaning of the MCFA.

82. Private enforcement under the MCFA is created under Minnesota Statute 325F.70, subd. 3:

> (a) In addition to the remedies otherwise provided by law, ***a consumer*** injured by a violation of sections 325F.68 to 325F.70, in connection with a sale of merchandise for personal, family, household, or agricultural purposes, ***may bring a civil action and recover damages, together with costs and disbursements, including costs of investigation and reasonable attorney fees, and receive other equitable relief as determined by the court***. An action brought under this section benefits the public.

(b) For the purposes of this subdivision:

(1) "consumer" means a natural person or family farmer; ….

(emphasis added).

83. Minnesota Statute 325F.70, subd. 3, provides that any remedies available under Chapter 325F are in addition to any other remedies otherwise available for the same conduct under state or local law, as referenced above.

84. As a result of Defendants' unfair and deceptive trade practices, Plaintiff and the Sub-Class members are entitled to an award of attorney's fees pursuant to Minn. Stat. 325D.70, subd. 3, if he prevails.

85. Wherefore, Plaintiff, and the Minnesota Sub-Class, pray for judgement against Defendants, as set forth hereafter. Defendants' conduct with respect to fraud, misrepresentation, and deceptive or unfair practices in connection with the sale of their Products is unfair because Defendant' conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

86. In accordance with Minn. Stat. 325F.70, subd. 3, Plaintiff and the Minnesota Sub-Class seek an order enjoining Defendants from continuing to conduct business through fraudulent or unlawful practices and to commence a corrective advertising campaign. Defendants' conduct is ongoing and continuing, such that prospective injunctive relief is necessary.

87. On behalf of Plaintiff and the Minnesota Sub-Class, Plaintiff also seeks an order entitling them to recover all monies spent on the Defendants' Products, which were acquired through acts of fraudulent, unfair, or unlawful competition, in accordance with Minn. Stat. 325F.70, subd. 3. In addition, the measure of restitution should be full refund of the purchase price insofar as the Products and their associated labels are worthless.

88. Wherefore, Plaintiff and members of the Minnesota Sub-Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the Products.

THIRD CAUSE OF ACTION

Violation of the Minnesota Unlawful Trade Practices Act

Minn. Stat. §§ 325D.09–325D.16

(On Behalf of the Plaintiff and the Minnesota Sub-Class Against All Defendants)

89. Plaintiff incorporates by reference and re-alleges each and every allegation contained about, as though fully set forth herein.

90. The Minnesota Unlawful Trade Practices Act ("MUTPA") is intended to protect consumers from being misled "as to the quality, ingredients and origin of merchandise purchased; that they deprive consumers of various customer services offered by regularly established and bona fide retail outlets without compensating advantage to consumers; and that they constitute unfair and fraudulent competition and unsound and uneconomic methods of distribution." Minn. Stat. § 325D.09.

91. Minn. Stat. 325D.13 provides: "No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise."

92. Defendants have engaged and continue to engage in knowing misrepresentation of the true quality of the phenylephrine contained in their Products.

93. By committing the acts alleged above, Defendants have engaged in knowing and deceptive misrepresentation, which constitute unfair competition within the meaning of MUTPA.

94. Private enforcement under MUTPA is created in Minn. Stat. 325D.15: "Any person damaged or who is threatened with loss, damage, or injury by reason of a violation of sections 325D.09 to 325D.16 shall be entitled to sue and have injunctive relief…and for the amount of actual damages, if any."

95. Minn. Stat. 325D.15 provides that injunctive remedies available under MUTPA are in addition to any other remedies otherwise available for the same conduct under state or local law, as referenced above.

96. Wherefore, Plaintiff, and the Minnesota Sub-Class, pray for judgement against Defendants, as set forth hereafter. Defendants' conduct with respect to misrepresentation in connection with the sale of their Products is unfair because Defendant' conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

97. In accordance with Minn. Stat. 325D.15, Plaintiff and the Minnesota Sub-Class seek an order enjoining Defendants from continuing to conduct business through fraudulent or unlawful practices and to commence a corrective advertising campaign. Defendants' conduct is ongoing and continuing, such that prospective injunctive relief is necessary.

98. On behalf of Plaintiff and the Minnesota Sub-Class, Plaintiff also seeks an order entitling them to recover all monies spent on the Defendants' Products, which were acquired through acts of fraudulent, unfair, or unlawful competition, in accordance with Minn. Stat. 325D.15. In addition, the measure of restitution should be full refund of the purchase price insofar as the Products and their associated labels are worthless.

99. Wherefore, Plaintiff and members of the Minnesota Sub-Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the Products.

FOURTH CAUSE OF ACTION

Unjust Enrichment

(On Behalf of the Plaintiff, the National Class, and the Minnesota Sub-Class Against All Defendants)

100. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

101. Plaintiff brings this Count individually and on behalf of the Minnesota Sub-Class.

102. Each Defendant profited exponentially from their marketing and sales of these products containing phenylephrine. Plaintiff and Sub-Class members were deprived of the money paid for these ineffective products.

103. Unjust enrichment is an equitable doctrine which allows a plaintiff to recover from a Defendant whenever the Defendant's retention of the benefit is not legally justifiable. *Caldas v. Affordable Granite & Stone, Inc.*, 820 N.W.2d 826, 838 (Minn. 2012), *overruled on other grounds*.

104. In an unjust enrichment case, a plaintiff must show that the defendant "has knowingly received or obtained something of value for which the defendant in equity and good conscious should pay." *ServiceMaster of St. Cloud v. GAB Business Services*, 544 N.W.2d 302, 306 (Minn. 1996) (internal quotations omitted).

105. Plaintiff and Sub-Class members were deprived of the money paid to Defendants for these ineffective products. It would be inequitable and unconscionable for each Defendant to retain the compensation obtained by each Defendant based on their wrongful conduct.

106. Wherefore, Plaintiff and members of the Minnesota Sub-Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the Products.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, pray for judgment against the Defendants as to each and every count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiff and his counsel to represent the Class/Sub-Classes, and requiring Defendants to bear the costs of class notice;

B. An order enjoining Defendants from selling the Products;

C. An order enjoining Defendants from suggesting or implying that they are effective for human application;

D. An order requiring Defendants to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as recalling existing Products;

E. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendants from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendants' past conduct;

F. An order requiring Defendants to pay restitution/damages to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising in violation of the above-cited authority, plus pre- and post-judgment interest thereon;

G. An order requiring Defendants to disgorge any ill-gotten benefits received from Plaintiff and members of the Class/Sub-Classes as a result of any wrongful or unlawful act or practice;

H. An order requiring Defendants to pay all actual and statutory damages permitted under the counts alleged herein;

I. An order awarding attorneys' fees and costs to Plaintiff and the Class/Sub-Classes; and

J. An order providing for all other such equitable relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated: November 9, 2023

/s/Amanda M. Williams

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